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Statement of Rep. Henry A. Waxman FDA's 100th Anniversary June 27, 2006

I'm pleased to be here with Michael Jacobson of the Center for Science in the Public Interest and Sid Wolfe of the Public Citizen Health Research Group. Both men and the organizations they run have been tireless advocates for public health and a strong FDA. And the American public should be deeply indebted to them.

On June 30, 2006, FDA will celebrate its 100th anniversary. Created following the passage of the Pure Food and Drug Act of 1906, the agency was born at a time when many foods were poisonous or rotten and many drugs were dangerous or useless. A century ago, FDA was established as a science-based agency whose guiding purpose was to protect the consumer. For the first time, the federal government would act to elevate the interests of public health and consumer safety above the interests of industry.

In the 100 years since its creation, FDA has accomplished many great things. Our food supply is immeasurably safer. Our drug approval process has been called the world's "gold standard." FDA pioneered the regulation of medical devices. And we once led the world in approving lifesaving AIDS and cancer drugs.

As an American, and as a close observer of FDA, I am proud of these accomplishments.

But on the occasion of its 100th anniversary, I see an agency that is adrift and floundering. The FDA that has achieved so much in the last century — and that was once the most respected regulatory agency in the world — has seen its powers wither and its reputation plummet over the last five years. Today, the agency's historic commitment to public health is in doubt.

There are many aspects of the agency's decline. One major problem is in the elevation of politics over science. The legacy of FDA is built on its scientific strength. Yet this Administration has ignored and twisted science to reach pre-ordained outcomes. Example A is Plan B.

A series of recalls of blockbuster drugs has further eroded public confidence in the agency.

At the same time, FDA's legendary enforcement presence has been crippled. A century ago, the agency's first leader, Harvey Wiley, launched enforcement campaigns to protect the nation from contaminated foods. In the 1980s and 1990s, FDA Administrator David Kessler rejuvenated the agency by initiating aggressive enforcement cases.

But a new investigation that I released yesterday shows how the Bush Administration has shackled FDA's enforcement division. Over the last five years, agency enforcement efforts have declined by 50%. Even when career inspectors identify violations that cause death or serious injury, FDA headquarters seems to sit idly by.

Yesterday, FDA claimed that one of the greatest enforcement triumphs under the Bush Administration was the seizure of almost \$1 billion worth of drugs in 2005. So overnight, my staff dug into the details of this case that FDA appears to be citing. We found that the actual facts of the case show agency neglect and dysfunctional enforcement, the exact opposite of what FDA said yesterday.

In 2005, FDA seized nearly a billion dollars worth of Paxil and other drugs produced by a GlaxoSmithKline facility in Cidra, Puerto Rico. But FDA field inspectors had documented serious violations at the plant in 2002, 2003, and 2004. Due to the lack of effective enforcement by FDA, these problems were not corrected. In April 2004 — a year before the seizure — the career field inspectors recommended that FDA order the plant to stop manufacturing the defective drugs. These recommendations were shunted aside, and FDA officials allowed the drugs to continue to be distributed to the public.

And even when FDA finally acted to seize some of the defective product, it did not order a recall of the drugs it was unable to seize. Nor did it fine the company for its record of persistent violations.

It's a sad but telling commentary that this is what passes for success at today's FDA.

I am deeply proud of the Food and Drug Administration, proud of all that it has accomplished over the last 100 years. But I'm also deeply worried about the agency's future. The agency needs to chart a new direction and once again make public health its first priority.